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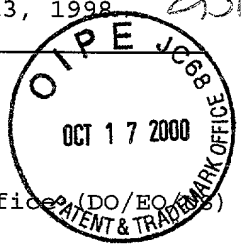
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		Attorney's Docket Number 08059.0004
		U.S. Application No. 09/622,094
International Application. No. PCT/NZ99/00016	International Filing Date February 9, 1999	Priority Date Claimed February 13, 1998

Title of Invention: DRUG DELIVERY SYSTEM

Applicants For DO/EO/US: Graham Francois DUIRS



Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [ ] This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. [X] This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. [ ] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [ ] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [ ] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:
    a. [ ] Verified Small Entity Statement.
    b. [X] Copy of Notification of Missing Requirements.

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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371	Attorney's Docket Number 08059.0004 U.S. Application No. 09/622094	
International Application. No. PCT/NZ99/00016	International Filing Date February 9, 1999	Priority Date Claimed February 13, 1998

Title of Invention: DRUG DELIVERY SYSTEM

CUSTOMER NUMBER 22852

Applicants For DO/EO/US: Graham Francois DUIRS

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

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2. [ ] This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
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   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
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U.S. APPLICATION NO. 09/622094	INTERNATIONAL APPLICATION NO. PCT/NZ99/00016	ATTORNEY DOCKET NUMBER 08059.0004

17. [X] The following fees are submitted:	CALCULATIONS
Basic National Fee (37 CFR 1.492(a)(1)-(5)):	
Search Report has been prepared by the EPO or JPO.....$840.00	$840.00
International preliminary examination fee paid to USPTO (37 CFR 1.482).....$670.00	
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....$690.00	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....$970.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4).....$ 96.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$970.00**
Surcharge of $130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$

Claims	Number Filed	Number Extra	Rate	
Total Claims	12-20=	0	X $18.00	$
Independent Claims	3- 3=	3	X $78.00	$
Multiple dependent claim(s) (if applicable)			+$260.00	$260.00
TOTAL OF ABOVE CALCULATIONS =				**$1230.00**
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28)				$
SUBTOTAL =				**$1230.00**
Processing fee of $130.00 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$
TOTAL NATIONAL FEE =				**$1230.00**
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).		$40.00 per property	+	$
TOTAL FEES ENCLOSED =				**$1230.00**
Amount to be refunded				$
charged				$

a. [X] A check in the amount of **$1230.00** to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of$_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-0916. A duplicate copy of this sheet is enclosed.

The Commissioner is hereby authorized to charge any other fees due under 37 C.F.R. §1.16 or §1.17 during the pendency of this application to our Deposit Account No. 06-0916.

SEND ALL CORRESPONDENCE TO:
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Submitted: August 11, 2000

DRUG DELIVERY SYSTEM

TECHNICAL FIELD

This invention relates to a substance delivery system.

Reference throughout the specification shall be made to the use of the present invention as a drug delivery system for use in animal body cavities, such as the vagina.

It should be appreciated however that the present invention can be used to deliver substances other than drugs and can be used in relation to humans and in other body cavities, for example the rumen, ears and so forth.

BACKGROUND ART

Drug delivery systems are used extensively in controlled breeding and reproductive management. Although considerable research has been invested in the design of these devices, there are still problems associated with them.

Firstly, these devices are required to be retained within the body cavity for the slow release of drugs over a period of time. To facilitate this, various arms and projections have been built into the device which can either engage with the walls of the body cavity, or make the device wide enough such that when in the body cavity it cannot naturally exit the animal through the entrance orifice.

Major problems with the provision of such arms or projections is that they can irritate or even rupture the lining of the body cavity, causing distress to the animal and providing a site for possible infection.

A major problem with drug delivery devices is that traditionally they have been manufactured with the drug impregnated into the material from which the device is

made. Typically, this material is in many instances a matrix of silicone.

To manufacture devices from drug impregnated silicone is expensive.

A further disadvantage of using a drug impregnated device is that it is very difficult to dispose. For example, the hormones used in reproductive management are required to be disposed in accordance with heavily regulated environmental procedures. As it is always possible that the drug within the silicone matrix had not been fully delivered to the animal when the device is removed, the whole device will have to be disposed as the whole device is the drug delivery system.

It would be desirable if the devices could be reused.

Another problem with the devices is that they have a specific dose rate which cannot be readily changed. Further with these devices, the treatment cannot be changed or customised according to requirements.

In some animals such as cows, the progesterone dose rate for synchronising oestrus is critical to the reproductive cycle. Typically, in the pre-luteal phase the animal will reproduce follicles which are the stage that ovum are produced. Follicule maturation then occurs and the follicule develops into the corpus luteum in the ovary. Fertilisation can then occur.

Therefore healthy follicules are a pre-requisite for conception.

Exogenous progesterone is often delivered to cows to inhibit follicle maturation as a means of synchronising oestrus. When the treatment is removed progesterone levels fall and the animals cycle in a controlled manner. If however the progesterone blood levels during treatment fall below critical levels oestrus synchronisation may still occur but follicle integrity may be compromised thereby reducing conception rates and fertility. This condition highlights the necessity to

maintain adequate progesterone dose using an efficient drug delivery system.

To maintain adequate dose previous drug delivery systems have contained excessively high progresterone dose levels. This has resulted in high residual levels of drug remaining in the device after use which has adverse economic and environmental impacts.

In addition, various applications of a treatment may require different drug delivery periods. For instance, one treatment may require six days drug delivery, another treatment may require ten days drug delivery. In this situation an ability to offer dose choice would be feasible. Also, very large animals of the European breeds may require larger doses than the smaller animals on pastoral systems in countries like New Zealand.

What would be desirable then is a drug delivery device that delivers the drug in a sufficient quantity over the treatment period with a minimum of residual drug remaining in the device matrix after treatment to achieve production economies and to avoid adverse environmental impacts caused by disposing used devices in land fills that contain large quantities of hormones. Flexibility in being able to change or customise the treatment would be desirable.

It is an object of the present invention to address the foregoing problems or at least to provide the public with a useful choice.

Further aspects and advantages of the present invention will become apparent from the ensuing description which is given by way of example only.

DISCLOSURE OF INVENTION

According to one aspect of the present invention there is provided a substance delivery device,

characterised in that the surface area of the substance dispenser is independent of the supporting structure of the substance delivery device.

The substance delivery device should now be referred to as a drug delivery device such as an intravaginal release device (IRD).

It should be appreciated however that a device in accordance with the present invention can be adapted for use in other body cavities such as the rumen, the auditory system, the gum area and other body cavities.

It should also be appreciated that the present invention can be used in both humans and animals.

In preferred embodiments, the present invention may be used in the treatment of cows.

The applicant has recognised that a dissolution process as a means of drug delivery is very effective provided the drug release process is controlled. The applicant has in his invention concentrated on the principles which aid dissolution, namely the surface area and thinness of the substance dispensers, surface area exposed directly to the body cavity and in some embodiments the holding of drugs in cavities in the dispenser.

It should be appreciated however that other drug delivery methods can be used such as mechanical or electronic.

The present invention can also be used to introduce a biological monitor such as a thermometer.

As a further issue the applicant has also been conscious of providing a ready

means by which the drug profile delivered by the substance delivery device can be readily modified. For example, different animal weights require different amounts of drugs.

The substance being delivered may come in a variety of forms. For example, these may be liquid, bullets, powder, gel, and other such forms. However, this list should not be seen to be exhaustive.

In one embodiment, the substance dispenser may be a pod with a housing containing vanes. Preferably, the pod may take the form of an obloid. The vanes may be positioned so that they are axially directed through the centre of the sphere and are in contact with the inside of the sphere at their outer edges.

Having one embodiment of the substance dispenser as a pod should not be seen to be limiting, as the principles of the present invention may be applied using a substance dispenser of a different configuration.

For example the substance dispenser may be a substantially cylindrical device containing vanes, or containing a grid, honeycomb or mesh arrangement. The grid, honeycomb or mesh arrangement may also be applied to the pod configuration for equal effectiveness.

In preferred embodiments, the dispenser may be a temporary attachment to a supporting structure, or could be applied as a permanent attachment to a supporting structure. In a further preferred one embodiment the dispenser may be a free-standing delivery pod within the body cavity.

Preferably the dispenser may be used as a temporary attachment to a supporting structure, such as can be found in New Zealand Patent Application No. 328967. Reference to the device in New Zealand Patent No. 328967 should not be seen to be limiting, as the supporting structure may constitute another form of device

while still maintaining the advantages of the dispenser.

In some embodiments in the present invention the dispenser may be used in conjunction with existing structures on the market such as those described in New Zealand Patent No. 207341. The substance delivery device disclosed in that patent application has substance to be delivered contained in the matrix of the supporting structure with all of the inherent problems described earlier in this patent specification. However, the present invention could be used to provide add-on substance delivery devices to its supporting structure which may either supplement or substitute for the substance contained within that supporting structure.

One advantage of configuring the dispenser as a pod containing vanes is that the pod has a large surface area, provides increased durability, and provides increased comfort to the animal to which the device is applied.

In further preferred embodiments, the dispenser may have the capability of having supplementary dispensers attached to an existing dispenser. These supplementary dispensers may be of any suitable shape, such as a cylindrical device, a grid arrangement or a honey-comb or mesh arrangement.

However preferably, the supplementary dispenser may be a substantially cylindrical device containing vanes extending towards the centre of the cylinder.

The above configuration of the supplementary dispenser is that this device may be co-operatively attached to the main dispenser, with greater co-operation between the two structures, due to the facing edges of the two dispensers being substantially the same configuration.

The advantage of a supplementary dispenser as discussed above will be discussed further on.

In preferred embodiments the support structure may be any device that maintains the structural rigidity of the substance delivery device. For example the support structure may be a frame, a system of struts, a cantilever support, an air cushion support, a hydraulically supported device, or some other means of support.

In preferred embodiments, the substance being delivered may be drugs such as hormone treatment substances, for example, progesterone. Reference to the substance being delivered shall hereafter be referred to as drugs, however this should not be seen to be limiting the scope of the present invention's manufacture or use, as other substances may be delivered by the present invention without departing from the present invention's scope of manufacture or use.

This should not be seen to be limiting as other drug delivery devices may be used.

For example, the drug delivery device may be a spine (support structure) with fingers or objects extending from the centre of the spine that carry the drug and such fingers or objects.

Alternatively, there may be a central fixture point with radially extending arms or fingers. The substance to be delivered may be coated or impregnated on these spines or fingers.

Other embodiments of the present invention may be used without departing from the scope of the present invention.

Preferably, the vanes may be coated or impregnated with the substance to be dispensed. This has a number of advantages.

The increased surface area of the IRD means that a greater rate of substance transfer may be achieved. Furthermore, the relatively thin nature of the vanes means that a substance that is contained within the material the vanes consist of,

may diffuse more quickly to the outside surface of the vane and be transferred to the animal. This means that a greater proportion of the drugs will be dispensed.

The ability to regulate the device surface area to influence dose levels and to regulate the dose profile through matrix thickness enables specific dose formulations to be delivered through design by varying vane sizes and thickness.

Therefore, the problems associated with residual progesterone in the device may be reduced or overcome. Reduced thickness of the vanes coupled with increased surface area creates more efficient drug transfer resulting in reduced residue. No drugs are associated with the support structure of the IRD.

Therefore, maximum release of drug to specific dose requirements is achieved also providing minimal residue and an ability to modify surface areas and matrix thickness to meet specific treatment needs. With progesterone treatment good synchrony and fertility rates may be achieved using considerably less progesterone and matrix raw material than existing technologies. Drug residue will be considerably less than existing technologies.

In further preferred embodiments, the vanes may be coated with different drugs and different combinations. This has an advantage that a multi drug dosing system may be implemented.

In some embodiments, the vanes may be configured so that they form a cavity within the drug delivery device. This has a number of advantages.

The first advantage is that the cavities provide an increased surface area whereby fluid which is body fluid may interact with the increased surface area in the cavity, thereby increasing the capacity for the device to dispense the particular drug desired.

Secondly the cavities provide a space whereby additional materials such as further drugs may be stored for release, improving the drug dispensing economy and storage capacity of the drug dispensing device.

A third advantage of the cavities is that a greater number of cavities provides for multi-dose variability within specific cavities, for delivery of various drug delivery profiles. Thus depending on the dosing required, the amount of drug and particular type of drug may be stored in a particular cavity.

The vanes or cavity surface may be covered with a biodegradable surface to rate release additional substance.

By combining various drugs with various vane thicknesses, the consumer may tailor the drug delivery and dosing to match the particular need of the animal. These needs may be in terms of a type of drug required to be dispensed, and the length of time the drug should be dispensed in.

Thus, various drug delivery profiles may be achieved.

In preferred embodiments, the vanes may not be surrounded by an outer wall and project directly into the body cavity - being directly exposed to the body fluids in which the drugs dissolve.

Thus the most appropriate dose may be selected and applied to each specific treatment, independent of the main carrier body. This may be selected on the basis of different dosing sizes for larger or smaller animals by weight, but other factors such as the age of the animal, and the medical condition of the animal or other conditions may be used.

The present invention may be manufactured from any substance capable of being impregnated or coated with, and then releasing a drug. For example the present

invention may be manufactured from plastic, kevlar™, wood, glass, silicone or other substances.

Preferably however, the present invention may be manufactured from plastics material, polymers or elastomers. The advantages this gives are that the plastic is easily manufactured into the desired shape, is cheap to manufacture, and is malleable so as to prevent irritation to the animal when in use.

In preferred embodiments the material from which the substance dispenser is biomedical silicone elastomer rubber (polydimethylsiloxane). The applicant has found that this material is soft, pliable, does not irritate body tissues and can carry release substances embedded in its matrix.

The feature of the present invention regarding the supplementary dispenser, enables increased control over dose variance. A supplementary dose or a half dose or other dose profiles may be applied by fixing a supplementary dispenser to the main carrier body or to the existing dispenser.

Thus, more than one substance may be delivered at a time.

The use of a dispenser provides the ability to replenish treatments or applications, and/or apply them for sustained periods by replacing the dispenser, or adding a supplementary dispenser.

The dispenser design maximises the surface area such that the dose can be enhanced. This is particularly useful when silicone or polymer type materials are used in the construction of the dispenser for delivering the substances via dissolution processes.

The thickness of the vanes can be modified and varied such that the drug delivery rates can be manipulated to suit the species and dose profiles required.

An example of the benefits of a dispenser application follows.

In the intravaginal delivery of progesterone in cattle, whereby progesterone is impregnated into a silicone matrix requiring a sustained dose of approximately two ng/ml of exogenous progesterone in the blood. If dose levels decline below this, the follicule condition is impaired and the desired conception rates from the treatment are not achieved after removal of the device.

Using the dispenser, various forms of drug delivery can be applied and are not limited to polymer-based dissolution systems. For example, the dispenser cavities could be loaded with substances using a biodegradable coating to regulate the release.

Alternatively an electronically controlled pump may be inserted in the dispenser to release the substance.

In a further preferred embodiment, biological monitor such as an electronic thermometer may be inserted into at least one dispenser to provide real time body temperatures. Alternatively, monitors to detect pH, trace elements, hormones, bateria or viruses may be used.

This has an advantage when determining and monitoring an animal's bodily functions, which may be used to determine the dose variants or drug delivery profile required.

In preferred embodiments, the substance dispenser is in the form of drug impregnated gills attached to the supporting structure. The surface area of the gills can control the amount of drug delivered and the thickness and number of the gills controls the duration of the dose, and the dose profile.

Surface area based on flaps or gills that have no "central spine" component (as in

CIDR patent) provides a pliable matrix and enables protruding shapes such as gills to be used as these can be compacted for insertion into the body cavity and do not irritate mucosa due to their softness and shape. The lack of a rigid spine component also reduces the overall mass of the device.

Therefore, the size of the gills can be used to modify the drug profile as required. Preferably, the profile has a fast drop off with little residual drugs as a consequence of applying these novel design concepts.

The gills may also be impregnated with different drugs.

In some embodiments, the gills may be of different types, for example, end gills and middle gills, wherein the end gills ensure the middle gills are secured with respect to the supporting structure.

The gills have a central aperture that allows them to be readily pushed onto (or pulled off) a supporting structure. This allows the number of gills and hence dosage amount to be readily changed. Also, only one supporting structure can be used for multiple treatments by removing expended gills and replacing them with fresh gills.

This leads to significantly less wastage than previous devices and less disposal problems.

In a preferred embodiment of the present invention, the gills are moulded into a sleeve which slides over an arm of the supporting structure. By having the gills moulded into the sleeve, the spacing between the gills can be optimised to ensure that there is no competition between the gills in terms of drug release and that the mucosal absorption is not overloaded.

In this latest embodiment, the dosage or treatments can be changed by removal of

the whole sleeve in replacement of a further one.

The sleeves may also be made with varying numbers of gills depending on the type or amount of treatment which is required to be given.

Preferably, the gills are made of a soft and pliable silicone. This aids animal comfort and welfare and in insertion and removal of the IRD with respect to body orifices. This allows certain configurations of IRDs to be compressed to a smaller size than more rigid devices.

BRIEF DESCRIPTION OF DRAWINGS

Further aspects of the present invention will become apparent from the following description which is given by way of example only and with reference to the accompanying drawings in which:

Figure 1 shows various views of a vaned pod embodiment, and

Figure 2 shows various views of gills used in one embodiments, and

Figure 3 shows various views of further variation of the pod in Figure 1, and

Figure 4 shows various views of different gill sleeves used in the present invention, and

Figure 5 shows a sleeve embodiment, and

Figure 6 illustrates a petal shaped variation of the gills.

BEST MODES FOR CARRYING OUT THE INVENTION

In the reference to Figure 1 there is shown a plan view of a substance dispenser in

the form of a pod generally indicated by arrow 1. The pod includes two half hemispheres (2), supporting vanes (3) and cavities (4).

In use, the pod (1) is attached to a support structure (not shown) before being inserted into the vagina of an animal such as a cow. The hemispheres (2) and the supporting vanes (3) may be coated with the drug that is required to be dispensed. The pod (1) may be fixed to an insertion device not shown.

The supporting vanes (3) may be used as a storage location for further drugs or other substances that are required to be released.

Each of the vanes (3) may be coated or impregnated with the same or a different substance. Similarly, the cavities (4) may hold additional drugs or substances required to be dispensed.

Figure 2 shows individual plates which in combination form gills generally indicated by arrow (5) which can be inserted into a support structure of an IRD.

The end gills (6) can be anchored to the support structure ensuring that the middle gills (7) which may sit loosely on the structure do not fall off.

Figure 3 illustrates a variation of the embodiment in Figure 1, without an outer shell allowing the vanes to have direct contact with body fluid.

Figure 3 illustrates three IRD's, each with the same supporting structure, but with substance dispensers having differing number gills.

The dispenser (12) in the form of a sleeve having gills (13) moulded therein. Sleeves (12) can be readily fitted over or removed from the arms (14) of the supporting structure (11).

It can be seen that initially different dose amounts can be introduced to the animals

by using different sleeves. It should also be seen that after treatment has commenced, there is still flexibility provided through the removal and replacement of the dispensers (12).

Figure 5 shows an alternate sleeve embodiment of an IRD generally indicated by arrow (20) with a gill sleeve (21) that is detachable.

Consequently, the consumer may design a particular drug delivery profile that is suited to the particular application and needs of the animal. The thickness of the vanes may be varied, to comply with the required dosing rate and drug delivery profile for the particular drug the vanes are impregnated or coated with. Similarly, the cavities in Figure 1 may contain an appropriate amount of the substance to be delivered, to comply with the particular drug delivery profile required to suit the particular needs of the animal.

Figure 6 illustrates some possible cross-sections of gills (15) in having petals (16). The applicant has found that petals provide greater flexibility/pliability to the gills (15) providing greater animal comfort and ease of insertion as well as enhancing the dissolution process.

Aspects of the present invention have been described by way of example only and it should be appreciated that modifications and additions may be made thereto without departing from the scope of the appended claims.

CLAIMS:

1. A substance delivery device, including a substance dispenser

characterised in that the surface area of the substance dispenser is independent of the supporting structure of the substance delivery device.

2. A substance delivery device as claimed in claim 1 in the form of a intravaginal release device.

3. A substance delivery device as claimed in either 1 or claim 2 for use with cows.

4. A substance delivery device as claimed in any one of claims 1 to 3, wherein the substance dispenser is a pod with housing containing vanes.

5. A substance dispenser as claimed in any one of claims 1 to 4 wherein the substance dispenser is in the form of fingers extending from the support structure.

6. A substance delivery device where the substance dispenser is in the form of drug impregnated or coated gills attached to the support structure.

7. A substance delivery device as claimed in either claim 4 or claim 5 wherein the vanes and/or fingers are coated or impregnated with the substance to be dispensed.

8. A substance delivery device as claimed in any one of claims 4 to 7, wherein the gills, vanes or fingers are coated or impregnated with different drugs and different combinations.

9. A drug dispensing dispensing device as claimed in claim 4 wherein the

vanes are configured to form a cavity within the drug delivery device.

10. A drug delivery device as claimed in any one of claims 1 to 9 wherein the substance dispenser is made from polydimethylsiloxane.

11. A substance delivery device as claimed in any one of claims 1 to 10 wherein the substance dispenser is highly flexible.

12. A substance delivery device as claimed in any one of claims 1 to 11 wherein the substance dispenser has essential aperture allowing the substance delivery device to slide over the support structure.

13. A substance delivery device wherein the substance dispenser is in the form of a sleeve which can slide over an arm of the support structure.

14. A substance delivery device substantially as herein described with reference to and as illustrated by the accompanying drawings.

15. A method of delivering drugs substantially as herein described with reference to the description within the specification.

CLAIMS:

1. A substance delivery device, including a substance dispenser fixed to a supporting structure by a releasable fixing means wherein the releasable fixing means includes a substance dispenser having a central aperture allowing the substance dispenser to slide over a corresponding section of the supporting structure and be readily removed from same, characterised in that the surface area of the substance dispenser is independent of the supporting structure and the substance dispenser is in the form of fingers extending from the support structure.

2. A substance delivery device as claimed in claim 1 wherein the said fingers are gills.

3. A substance delivery device as claimed in claim 1 wherein the said fingers are vanes.

4. A substance delivery device as claimed any one of claims 1 to 3 wherein the fingers are coated or impregnated with the substance to be dispensed.

5. A drug delivery device as claimed in any one of claims 1 to 4 wherein the substance dispenser is made from polydimethylsiloxane.

6. A substance delivery device as claimed in any one of claims 1 to 5 wherein the substance dispenser is highly flexible.

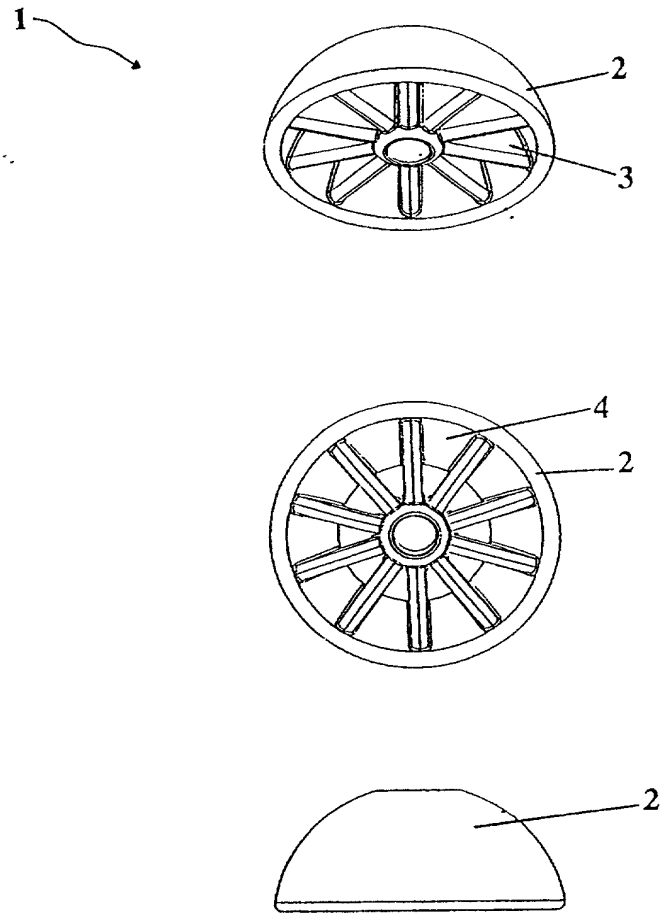
7. A substance delivery device as claimed in any one of claims 1 to 6 in the form of a intravaginal release device.

8. A substance delivery device as claimed in any one of claims 1 to 7 for use with cows.

9. A substance delivery device substantially as herein described with reference to and as illustrated by the accompanying drawings.

10. A method of delivering drugs substantially as herein described with reference to the description within the specification.

Figure 1



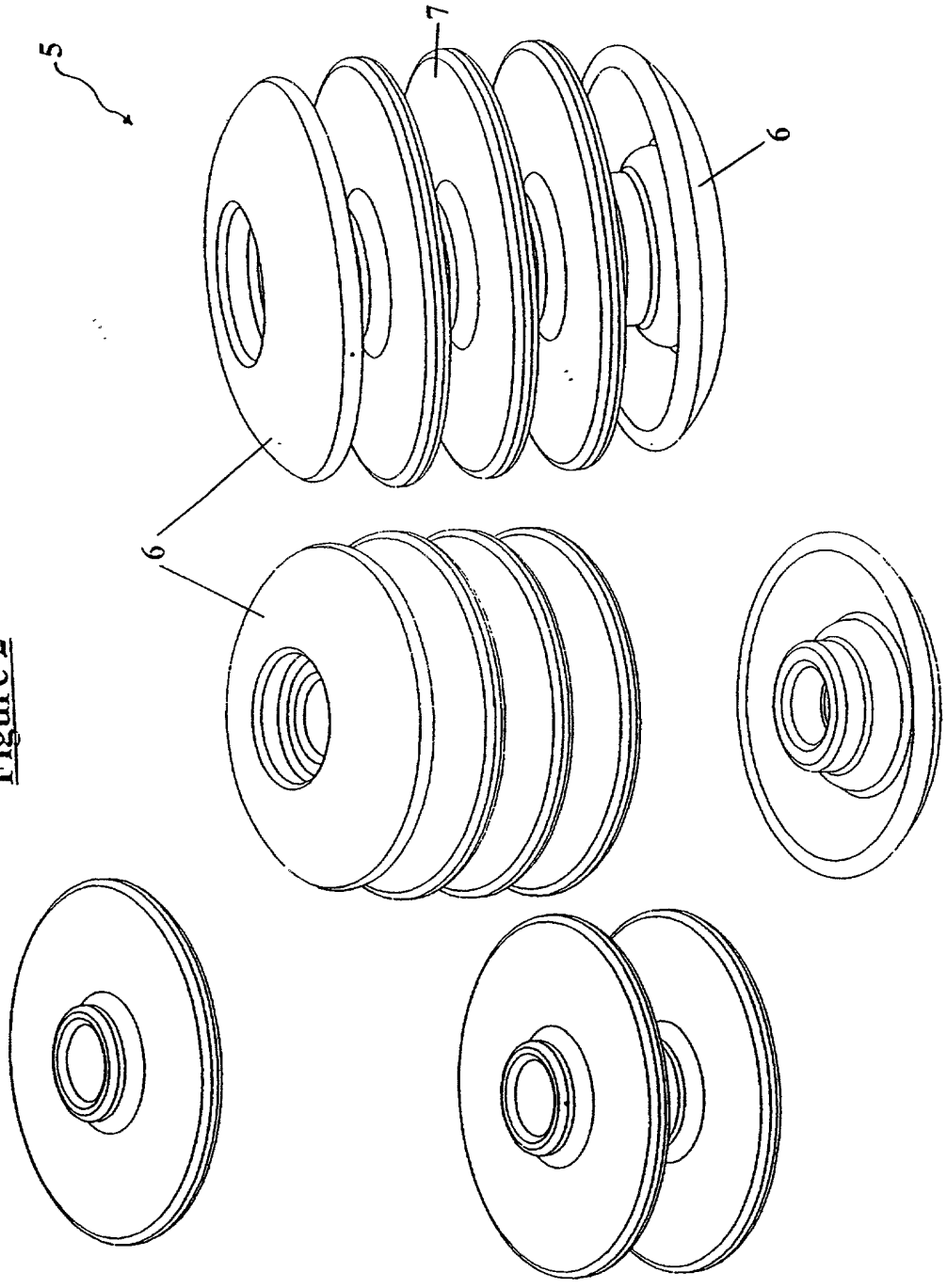
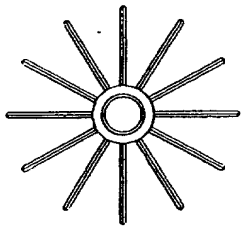
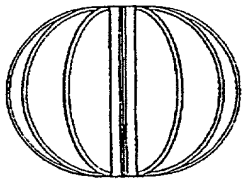


Figure 2

Figure 3





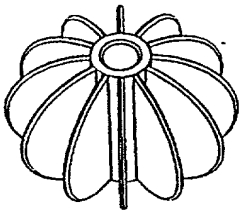


Fig. 4

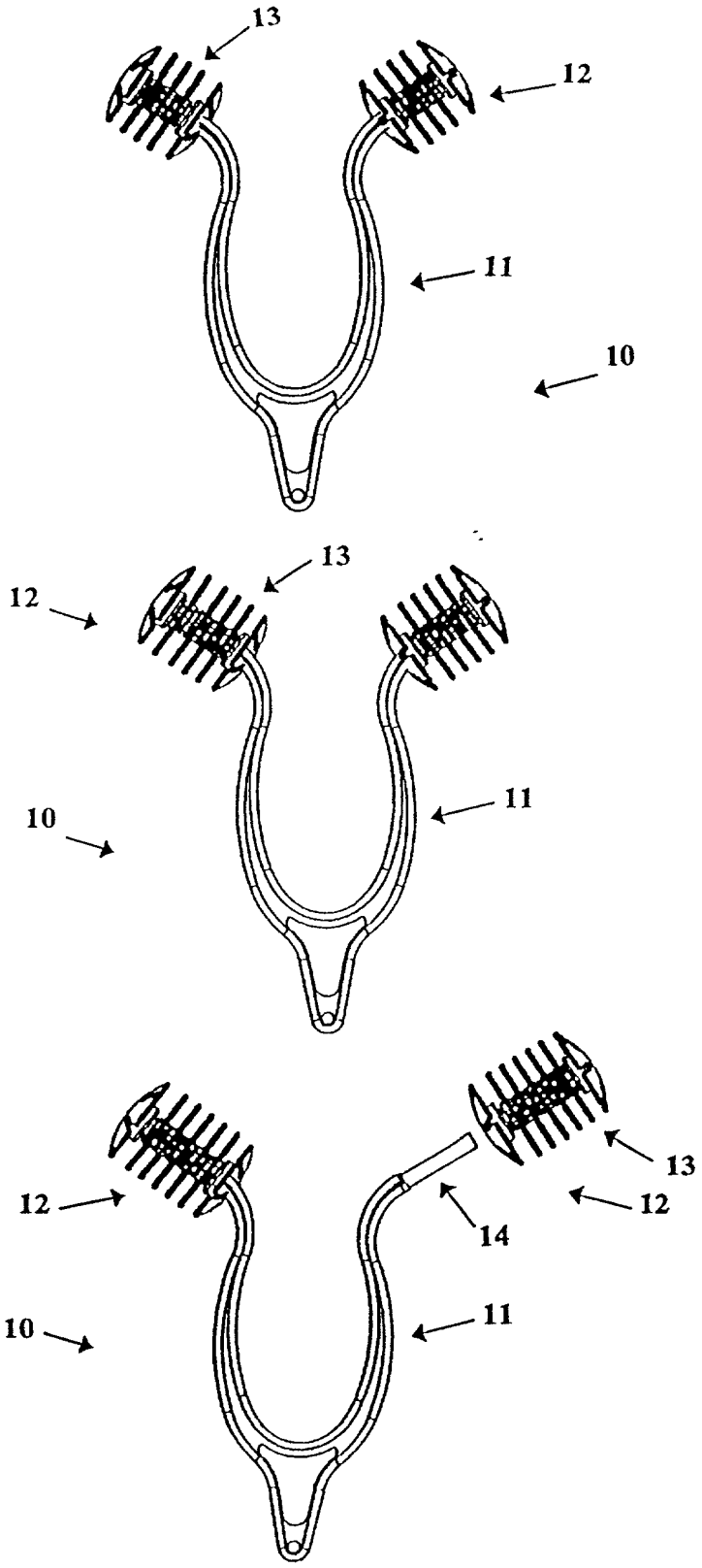


Fig. 5

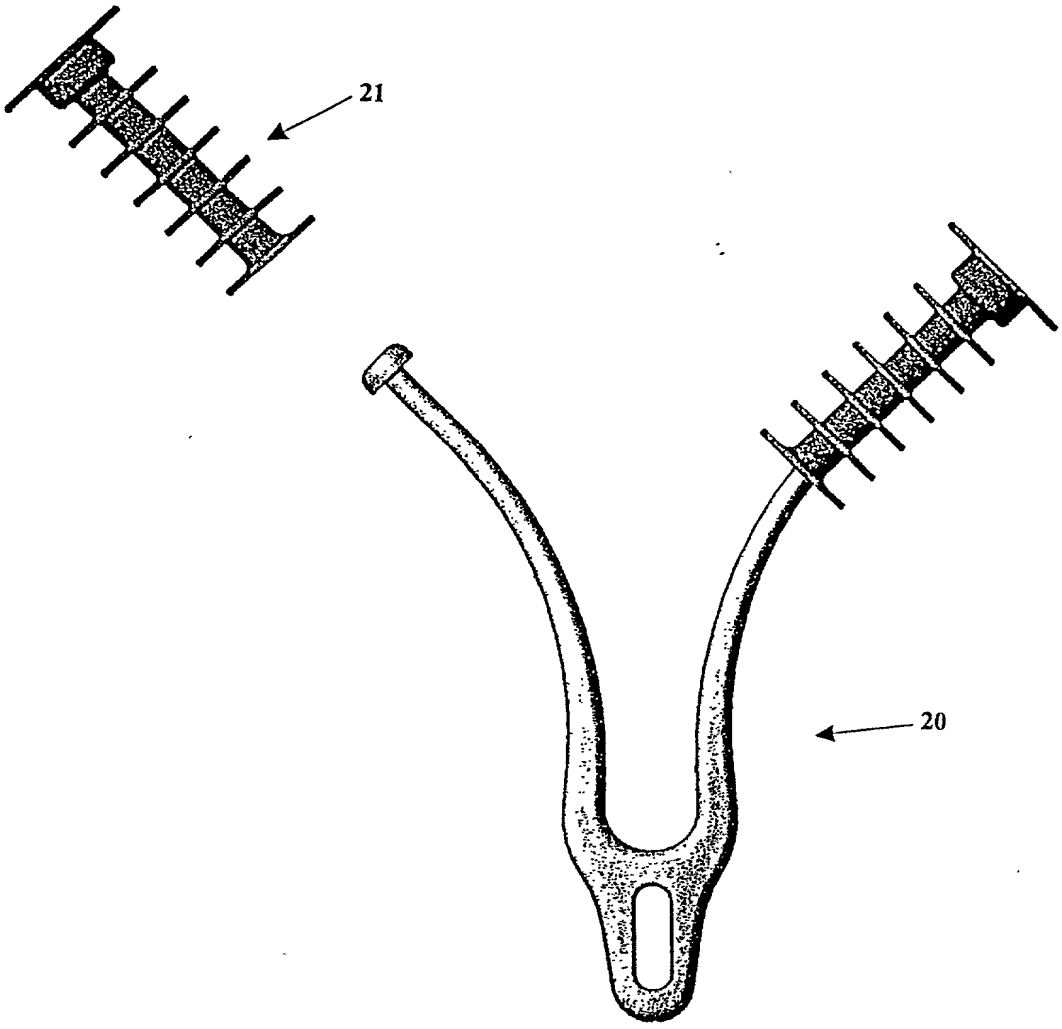
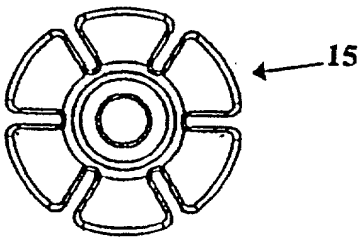
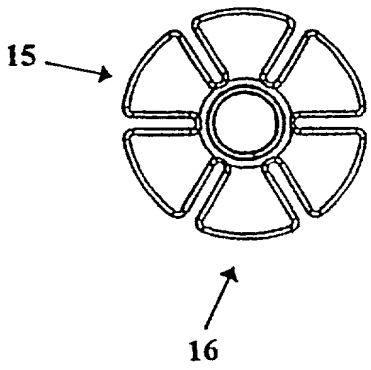


Fig. 6





Attorney Docket No. _____

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Drug Delivery System

the specification of which ☐ is attached and/or ☐ was filed on 11 August 2000 as United States Application Serial No. _____ or PCT International Application No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate or § 365(a) of any PCT international application(s) designating at least one country other than the United States, listed below and have also identified below, any foreign application(s) for patent or inventor's certificate, or any PCT International application(s) having a filing date before that of the application(s) of which priority is claimed:

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C.
New Zealand	329799 332795	13 February 1998 13 November 1998	☐ YES ☐ NO
PCT	PCT/NZ99/00016	9 February 1999	☐ YES ☐ NO

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Number	Date of Filing

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) or § 365(c) of any PCT International application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application(s) in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application(s) and the national or PCT International filing date of this application:

Application Number	Date of Filing	Status (Patented, Pending, Abandoned)

I hereby appoint the following attorney and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Douglas B. Henderson, Reg. No. 20,291; Ford F. Farabow, Jr., Reg. No. 20,630; Arthur S. Garrett, Reg. No. 20,338; Donald R. Dunner, Reg. No. 19,073; Brian G. Brunsvold, Reg. No. 22,593; Tipton D. Jennings, IV, Reg. No. 20,645; Jerry D. Voight, Reg. No. 23,020; Laurence R. Hefter, Reg. No. 20,827; Kenneth E. Payne, Reg. No. 23,098; Herbert H. Mintz, Reg. No. 26,691; C. Larry O'Rourke, Reg. No. 26,014; Albert J. Santorelli, Reg. No. 22,610; Michael C. Elmer, Reg. No. 25,857; Richard H. Smith, Reg. No. 20,609; Stephen L. Peterson, Reg. No. 26,325; John M. Romary, Reg. No. 26,331; Bruce C. Zotter, Reg. No. 27,680; Dennis P. O'Reilley, Reg. No. 27,932; Allen M. Sokal, Reg. No. 26,695; Robert D. Bajefsky, Reg. No. 25,387; Richard L. Stroup, Reg. No. 28,478; David W. Hill, Reg. No. 28,220; Thomas L. Irving, Reg. No. 28,619; Charles E. Lipsey, Reg. No. 28,165; Thomas W. Winland, Reg. No. 27,605; Basil J. Lewris, Reg. No. 28,818; Martin I. Fuchs, Reg. No. 28,508; E. Robert Yoches, Reg. No. 30,120; Barry W. Graham, Reg. No. 29,924; Susan Haberman Griffen, Reg. No. 30,907; Richard B. Racine, Reg. No. 30,415; Thomas H. Jenkins, Reg. No. 30,857; Robert E. Converse, Jr., Reg. No. 27,432; Clair X. Mullen, Jr., Reg. No. 20,348; Christopher P. Foley, Reg. No. 31,354; John C. Paul, Reg. No. 30,413; Roger D. Taylor, Reg. No. 28,992; David M. Kelly, Reg. No. 30,953; Kenneth J. Meyers, Reg. No. 25,146; Carol P. Einaudi, Reg. No. 32,220; Walter Y. Boyd, Jr., Reg. No. 31,738; Steven M. Anzalone, Reg. No. 32,095; Jean B. Fordis, Reg. No. 32,984; Barbara C. McCurdy, Reg. No. 32,120; James K. Hammond, Reg. No. 31,964; Richard V. Burgujian, Reg. No. 31,744; J. Michael Jakes, Reg. No. 32,824; Thomas W. Banks, Reg. No. 32,719; Christopher P. Isaac, Reg. No. 32,616; Bryan C. Diner, Reg. No. 32,409; M. Paul Barker, Reg. No. 32,013; Andrew Chanho Sonu, Reg. No. 33,457; David S. Forman, Reg. No. 33,694; Vincent P. Kovalick, Reg. No. 32,867; James W. Edmondson, Reg. No. 33,871; Michael R. McGurk, Reg. No. 32,045; Joann M. Neth, Reg. No. 36,363; Gerson S. Panitch, Reg. No. 33,751; Cheri M. Taylor, Reg. No. 33,216; Charles E. Van Horn, Reg. No. 40,266; Linda A. Wadler, Reg. No. 33,218; Jeffrey A. Berkowitz, Reg. No. 36,743; Michael R. Kelly, Reg. No. 33,921; James B. Monroe, Reg. No. 33,971; Doris Johnson Hines, Reg. No. 34,629; Allen R. Jensen, Reg. No. 28,224; Lori Ann Johnson, Reg. No. 34,498; and David A. Manspeizer, Reg. No. 37,540 and _____. Please address all correspondence to FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 1300 I Street, N.W., Washington, D.C. 20005, Telephone No. (202) 408-4000.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Listing of Inventors Continued on Page 2 hereof. ☐ Yes ☐ No